EXHIBIT D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD

April 23, 2021

Janssen Biotech, Inc.
Attention: Ms. Ruta Walawalkar
920 Route 202
Raritan, NJ 08869

Re: EUA 27205 - Emergency Use Authorization of Janssen COVID-19 Vaccine, Issued on February 27, 2021, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3)
Multiple Amendments dated April 20, 2021 - April 23, 2021 to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), the Authorized Fact Sheet for Recipients and Caregivers.

Dear Ms. Walawalkar:

This letter is to notify you that we have reviewed the changes in response to our requested revisions to your Authorized Fact Sheets and that these changes to your Authorized Fact Sheets are granted.

We concur with the updates to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following changes and clarifications:

WARNINGS AND PRECAUTIONS

- Subsection 5.2 'Thrombosis with Thrombocytopenia' including the information below was added to this section:
- Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination.
- Most cases of thrombosis with thrombocytopenia reported following the Janssen COVID-19 Vaccine have occurred in females ages 18 through 49 years; some have been fatal.
- Specific risk factors for thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine and the level of potential excess risk due to vaccination are under investigation.
- Based on currently available evidence, a causal relationship between thrombosis with thrombocytopenia and the Janssen COVID-19 Vaccine is plausible.
- Healthcare professionals should be alert to the signs and symptoms of thrombosis with thrombocytopenia in individuals who receive the Janssen COVID-19 Vaccine.
- The clinical course shares features with autoimmune heparin-induced thrombocytopenia.
- In individuals with suspected thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed.

- Consultation with hematology specialists is strongly recommended.
- The American Society of Hematology has published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine. (https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia)
- Recipients of Janssen COVID-19 Vaccine should be instructed to seek immediate medical attention if they develop shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms (including severe or persistent headaches or blurred vision), or petechiae beyond the site of vaccination.

OVERALL SAFETY SUMMARY

The following information was added to this section:

- Thrombosis involving large blood vessels, including the cerebral venous sinuses, portal vein, lower extremity veins, and pulmonary artery, with thrombocytopenia have been reported following the Janssen COVID-19 vaccine.

Clinical Trials Experience, Serious Adverse Events (SAEs) and other events of interest

- Information was added to convey that the case of transverse sinus thrombosis observed in study COV3001 also included thrombocytopenia and that onset of symptoms was 8 days post-vaccination.
- Clarification was made to state that for adverse events for which imbalances were observed in vaccine recipients compared to placebo recipients, a causal relationship with the Janssen COVID-19 Vaccine could not be determined based on study COV3001.
- The following information was also added: However, taking into consideration post-authorization experience, a causal relationship with Janssen COVID-19 Vaccine is plausible for thrombosis with thrombocytopenia.

Post Authorization Experience

Subsection 6.2 'Post Authorization Experience" including the information below was added:

- The following adverse reactions have been identified during post-authorization use of the Janssen COVID-19 Vaccine. Thrombosis involving large blood vessels, including the cerebral venous sinuses, portal vein, lower extremity veins, and pulmonary artery, combined with thrombocytopenia.

Minor editorial changes to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) were made for clarity and consistency. In addition, other changes consistent with those described above were made to the Short Version of the Fact Sheet.

In addition, the EUA Fact Sheet for Recipients and Caregivers has been updated: to include information about the remote risk of blood clots that involve blood vessels in the brain, abdomen, and legs, along with low levels of platelets; to note that most people who developed these blood clots and low levels of platelets were females ages 18 through 49 years; to note that for people who have developed blood clots and low levels of platelets following vaccination, symptoms began approximately one to two-weeks following vaccination; and to inform vaccine recipients that they should seek medical attention right away if they have any of the following symptoms after receiving Janssen COVID-19 Vaccine: shortness of breath, chest pain, leg swelling, persistent abdominal pain, severe or persistent headaches or blurred vision, or easy bruising or tiny blood spots under the skin beyond the site of the injection.

By submitting these amendments for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the February 27, 2021, letter re-authorizing the emergency use of Janssen COVID-19 Vaccine.

Sincerely,

--/S/--

Marion Gruber, PhD
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research